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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,195	04/25/2007	Marcus Vetter	085449-0203	6937

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EXAMINER	
ROY, BAISAKHI	
ART UNIT	PAPER NUMBER
3777	

MAIL DATE	DELIVERY MODE
04/19/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,195	VETTER ET AL.	
	Examiner	Art Unit	
	BAISAKHI ROY	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-30* is/are pending in the application.

5a) Of the above claim(s) *17-22* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-16 and 23-30* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/5/11 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims have been considered but are moot because the arguments do not apply to the combination of references being used in the current rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation "**the** course" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "**the** previous distance" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claims 7, 10, 11, and 12 recites the limitation "**the** transformation" in line 1, line 2, line 3, and line 1, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "**the** cyclical movements" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "**the** components" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "**the** central lines" in 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "**the** ramifications" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "**the** surface" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 24 and 26 recites the limitation "**the** surrounding tissue" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 recites the limitation "**the** cyclical movements" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-15 and 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi (7844320) in view of Downey et al. (6423009), with

evidentiary support from Michaeli et al. (2008/0319268) and evidentiary support from Xiao (7115124).

Shahidi discloses a method for navigation during medical interventions by recording and storing static image data of the organ structure before the intervention (col. 6 lines 42-51) using endoscopy.

Shahidi is directed to neurosurgery and tracking lesions in the brain of the patient using an endoscope. Endoscopy procedures are used to evaluate hollow cavity of a region of interest inside the body. In this reference, the inside of the brain is evaluated. As evidenced by Michaeli et al. (2008/0319268), the opening into the depths of the brain is tubular to allow for the use of endoscopes [0038]. Therefore, the Shahidi procedure is directed to a tubular organ structure.

Shahidi clearly teaches obtaining pre-operative image data or static image data where the images of the patient have been previously obtained, recorded or loaded, and stored into the computer memory (col. 6 lines 38-51). The “pre-op" protocol is used to obtain the static or pre-op image (col. 7 lines 14-16). The reference doesn't just assume that the images have been previously obtained. It explicitly teaches that the image data was "previously obtained". The reference details the process of the “pre-op protocol”. The recording is successively improved or updated at certain time intervals or during the surgical procedure (col. 7 lines 32-35) and recorded information can be used at a later time or made available for further use according to subsequent protocols (col. 7 lines 35-37). Therefore, the recorded images would be made available at a later point in time and would necessarily be used in the same format as they were recorded, as static or

pre-operative image data (col. 7 lines 56-64). Shahidi teaches segmenting out or extracting the organ structures (col. 6 lines 59-63, col. 13 lines 65-col. 14 line 5).

This is followed by converting the course of the organ structure into geometric description used during the medical intervention for instrument 109/organ 117 recording where the geometric description includes central lines and ramifications of the organ structure and is represented in different colors to represent different type of structures (col. 6 lines 63-col. 7 line 2). Shahidi teaches generating a geometric solid image of the internal structures inside the organ which is scanned to generate "pre-op" image data (col. 11 lines 4-9) where the display 1201 shows the surface contour lines or ramifications of the organ structure (col. 11 lines 22-26). Shahidi further teaches conducting surface rendering techniques to represent the surface contours or lines or ramifications of the organ structure (col. 11 lines 63-65).

The instrument 109 is spatially localized by a tracking system or optical tracking system having a sensing unit 105 (col. 5 lines 49-52). The instrument tip 115 is recorded as the spatial position of the instrument (col. 6 lines 10-12). The instrument includes several LEDs 110, 111 mounted on it (fig. 1) which allows tracking and recording of the instrument position along several positions along the instrument (col. 5 lines 54-58). The instrument is successively corrected in relation to the static data by a transformation that is preferably defined by an optimization method where Shahidi teaches continually updating the displayed images during the surgical procedure and the resulting displays are constantly refreshed in real-time due to changes in the position and orientation of the surgical instrument (col. 7 lines 29-37). Therefore, the

reference clearly teaches making changes or successive corrections based on changes of the instrument position and extracting features of interest from the static previously obtained image data.

Shahidi teaches tracking or monitoring or taking into account information on the previous distance or path covered by the incision device through tissue by displaying the data set where the surgeon can monitor every step of the incision as he or she moves through the tissue (col. 13 lines 50-59). Shahidi teaches the use of geometric transformation and perspective-view characterizations to provide the realistic simulation of the camera's field of view providing information and description on the distance covered by the surgical instrument (col. 14 lines 27-67). Therefore, Shahidi details the procedure involving obtaining and storing collated or integrated image data before the intervention, extraction of organ structures of interest from the static image data, converting the course of the organ structures into geometric description and localizing the instrument by tracking it and correcting position of the instrument based on distance covered by the instrument and making corrections in relation to the instrument data (fig. 16, col. 13 lines 60-col. 14).

The method also involves applying external or internal markers 113, 114 and the movement of the tubular organ structure is recorded and included in the calculation of the transformation (col. 5 lines 38-42, col. 12 lines 28-38, col. 18 lines 43-56). Therefore the images are recorded by registering the instrument position in real time resulting in continually updating the images during the procedure (col. 7 lines 29-37).

Shahidi teaches monitoring the movement of the patient's anatomy 1505 (col. 13 lines 2-22) but does not explicitly teach calculating the movement of the tubular organ structures from a changing position of the instrument. In the same field of endeavor Downey et al. teach a method for navigation during medical interventions on organ structures where the organ movement dependent on the changing position or placement of the instrument (col. 11 lines 16-21). The organ structure may be the prostate and as evidenced by Xiao (7115124), the prostate may be considered a tubular organ structure (col. 5 lines 13-14). Therefore, Downey et al. procedure is directed to a tubular organ structure.

Downey et al. teach that the position of the instrument is continuously updated with the relative translations caused by the organ movement (col. 11 lines 65-67). Downey et al. specifically teach calculating changes in position of the target organ from the changing position of the instrument (col. 11 lines 59-67). Downey et al. teach that the movements represent respiratory movements or breathing movements (col. 13 lines 43-45). Therefore, the movement of the organ structure is based on the position of the instrument as system calculates the path of the instrument to the target where the position of the instrument is recorded continuously or in real time (col. 10 lines 50-65) and necessarily includes tracking the movement of the organ. The movement of the instrument is at an angle or orthogonal to the organ structure where the path of the instrument is at an oblique angle to the target organ, perpendicular to the calculated trajectory path (col. 11 lines 6-11).

With respect to taking into account a generalized model of the anatomical structure and the surrounding tissue, in calculating the position, Downey et al. operate by reconstructing a three-dimensional model of the target volume and using the three-dimensional model to track the real-time two-dimensional image to compensate for organ movement and help in instrument placement (col. 11 lines 18-21, col. 12 lines 21-42, col. 13 lines 35-42). The anatomical structure is represented by the target volume and the surrounding tissue of the organ structure is represented by the organ (col. 13 lines 50-54). The model is necessarily a patient-specific model since it is catering to the respiratory movement of the patient (col. 14 line 65-col. 15 line 5).

The movements caused by respiratory or breathing movements are therefore dependent on the chronologically changing position or placement of the instrument (col. 11 lines 18-21) where the organ image is recorded by registering the instrument position (col. 12 lines 22-26). The position of the movement of the organ structure is determined from changing position of the instrument in real-time or based on the chronologically changing position of the instrument (col. 14 lines 34-37). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Downey et al. to modify Shahidi to provide a more accurate way of placing or tracking instrument position in light of the effect of moving organs or to compensate for organ movement (col. 11 lines 65-67, col. 13 lines 34-35).

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Downey et al. and further in view of Green. Shahidi teaches a neurological surgical procedure using an endoscope but does not teach the use of the method in

bronchoscopy interventions. In the same field of endeavor Green teaches a system and method for endoscopic imaging and surgery including bronchoscopy interventions to track a tubular organ structure (col. 3 lines 40-col. 4 line 5). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Green to modify Shahidi to conduct a bronchoscopy procedure in place of an endoscopy procedure to implement the method using an alternate intervention procedure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (9:00 a.m. - 5:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR
/Baisakhi Roy/
Examiner, Art Unit 3777